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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,646	12/07/2001	Peter W. Bringmann	BERLX 87	7678

7590 02/14/2005

NEIL G. MIYAMOTO
BERLEX BIOSCIENCES
2600 HILLTOP DRIVE
P.O. BOX 4099
RICHMOND, CA 94804-0099

EXAMINER	
SAOUD, CHRISTINE J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,646	BRINGMANN ET AL.	
	Examiner	Art Unit	
	Christine J. Saoud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December, 19 November, 17 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36-41 and 69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-41 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-35, 42-68 and 70 have been canceled and claims 36, 39, 40 and 41 have been amended in the response of 06 December, 19 November, and 17 August 2004. Claims 36-41 and 69 are pending and under consideration in the instant Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 17 August 2004 have been fully considered but they are not deemed to be persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 40 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 40 recites "wherein said polypeptide has 94% sequence identity to amino acid 1 to amino acid 208 of human FGF-9", however, this is no basis in the specification as originally filed for "94%". The claim previously indicated "95%" which find basis at page 5, line 11 of the specification, but the specific limitation of "94%" is not contemplated in the specification and therefore, appears to be new matter.

Claim Rejections - 35 USC § 103

Claims 36-41 and 69 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (Multiple Sclerosis 3: 113-120, 1997) in view of Nakamura et al. (Glia 28: 53-65, 1999) for the reasons set forth in the previous Office action.

Applicant argues at page 4 of the response that "neither Webster nor Nakamura et al. teach or suggest the administration of FGF-9 for the treatment of MS". Applicant is correct in this statement, which is why the rejection was made under the provision of 35 U.S.C. 103(a). If Webster or Nakamura had taught the administration of FGF-9 for the treatment of MS, the rejection would have been anticipatory and not obvious in nature.

Applicant additionally argues that Webster teaches that the increased proliferation of oligodendroglia by FGF, IGFI and PDGF is seen in rodent cultures but not in human cultures and therefore, Webster teaches away from the claimed invention. This argument is not persuasive for a number of reasons. First, this statement by Webster is in reference to the fact that growth factor-induced responses of human and rodent oligodendroglia in culture can differ (see page 114, column 1, final paragraph).

However, proliferation of these cells is only one aspect of treatment that would be useful for the treatment of MS; the suggestion of Webster is that growth factors could increase proliferation, enhance differentiation, upregulate synthesis of myelin and promote myelin regeneration, all of which would play a role in treatment of MS. Furthermore, Webster teaches that FGF (aFGF and bFGF) have mitogenic effects on the CNS and are involved in the differentiation of neurons and glia as well as being a major mitogen for cells in the oligodendroglial lineage (see page 116, column 2). Based on this complete disclosure of Webster, one of ordinary skill in the art would clearly conclude that growth factors, including FGF molecules, would be useful in the treatment of MS.

Applicant's citation regarding the difference in rodent cultures versus human cultures also raises a second grounds of argument that Webster is teaching away from the invention because *in vitro* data from rodent cells is not predictive of data from human cells. However, this argument is in direct conflict with the disclosure of the instant specification which relies on rodent cell culture data to claim a method of treating MS. Page 33 of the specification indicates that rat oligodendrocyes were used to measure cell proliferation and page 34 indicates that neuronal survival assays were conducted using "cells of neuronal origin" and page 35 indicates that neurite outgrowth was measured using PC 12 cells, which are cells obtained from rat adrenal gland. The only data presented for FGF-9 in the instant specification is based on activity seen *in vitro* on cells of rat origin. Therefore, it is clear that applicant has conceded that experimental evidence of biological activities obtained using rat cell cultures is predictive of biological activities *in vivo* and in humans based on the claims which are

presented in the instant application. If this is not the case, then the claims may be reevaluated for enablement issues based on Applicant's arguments.

Therefore, one of ordinary skill in the art at the time of the instant invention would have reasonably concluded that the biological activity of FGF-9 demonstrated by Nakamura et al. would be useful for treatment of conditions of the CNS which require stimulatory activity on astrocytes, motor neurons, and cells of the oligodendrocyte lineage. Furthermore, based on the teachings of Webster that growth factors would be useful for treatment of MS if they had biological activities such as the ability to increase proliferation and/or differentiation of oligodendrocytes, upregulate synthesis of myelin constituents, and promote myelin regeneration in the CNS, it would have been *prima facie* obvious to use the protein of Nakamura et al. for treatment of MS since the FGF-9 protein possesses some of these activities, absent evidence to the contrary.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud